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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/936,151 | 04/15/2002 | Keiji Fujii | JJM-472 | 9354 |

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EXAMINER

JASTRZAB, KRISANNE MARIE

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1744

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,151

Applicant(s)

FUJII ET AL.

Examiner

Krisanne Jastrzab

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/02, 3/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are found to be vague and indefinite because they fail to properly further limit the claims from which they depend. They depend from apparatus claims, but merely recite method limitations which fail to further define the structure. Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kaye U.S. patent No. 4,590,037.

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Kaye teaches a means for introducing coactive sterilizing agents into a chamber wherein the agents are contained separately on a chamber which is accessed by a piercing mechanisms such that it pierces the plural sterilizing agent containers and provides for their delivery to a sterilization chamber. See figure 3, column 4, lines 19-68 and column 6, lines 15-23.

Claims 1 and 10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by DE 2206910. See figures 3 and 4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alessi et al., U.S. patent No. 3,650,038 in view of Kaye U.S. patent No. 4,590,037.

Alessi et al., teach the delivery of a gaseous sterilant to a sterilization chamber from an individual container placed in a support chamber such that it can be pierced by automatically actuated piercing means to release the sterilant. See column 2, lines 50-68 and the figures.

Kaye teaches a similar delivery device with plural individual containers within the support chamber.

It would have been obvious to one of ordinary skill in the art to employ a plurality of sterilant containers within the containment support of Alessi et al., as taught in Kaye because it would minimize required user handling and downtime of the sterilizer by providing plural batch doses the sterilant for plural batches of sterilization.

With respect to claims 3, 6-7 and 9, Alessi et al., teach the containment of a gaseous sterilant and Kaye teaches the same containment for a liquid sterilant, and thus it would have been well within the purview of one of ordinary skill in the art to employ containers having both kinds of sterilant, as both are recognized as being effectively delivered in the same context and because it would enhance the overall applicability of the sterilizer in being equipped for both types of sterilization.

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Claim 8 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alessi et al., and Kaye as applied to claims 1-7 and 9-12 above, and further in view either Malchesky U.S. patent No. 5,858,305 or Siegel et al., U.S patent No. 5,662,866.

Both Malchesky and Siegel et al., teaches the known and expected use of puncturable containment means for sterilization apparatus. Both further teach the known and expected use of hydrogen peroxide and peracetic acid in such sterilization fields.

It would have been obvious to one of ordinary skill in the art to employ the sterilant solutions disclosed in Malchesky and Siegel et al., because of the recognized efficacy in the field and its recognized use with puncturable delivery devices.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alessi et al., together with Kaye as applied to claims 1-7 and 9-12 above, and further in view of Lin et al., U.S. patent No. 5,770,739.

Lin et al., teach the known and expected activation of a plasma for sterilization utilizing a sterilizing agent first provided in liquid form.

It would have been well within the purview of one of ordinary skill in the art to apply an activating plasma to the sterilizing agents released by the combination above because the presence of free radicals greatly enhances sterilization.

Conclusion

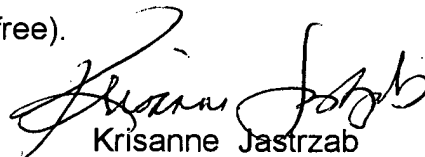
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krisanne Jastrzab whose telephone number is 571-272-

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1279. The examiner can normally be reached on Mon.-Wed. 6:30am-4:00pm and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Krisanne Jastrzab
Primary Examiner
Art Unit 1744
March 21, 2005